REMARKS/ARGUMENTS

Claim Status/Support For Claim Amendments

In response to the Office Action of March 11,2003, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim 1 has been amended. Claims 2-35 have been canceled. Claims 36-43 have been added. Claims 1 and 36-43 are pending in the instant application.

No new matter has been added by the addition of new claims 36-43. The subject matter of new claims 36-43 corresponds to the subject matter of canceled claims 2-35. The above additions to the claims also find basis in the original disclosure at page 12, lines 2-12; page 17, lines 7-14; page 18, lines 5-7 and page 27, line 17 to page 28, line 2. The method of claims 36-40 is described in detail at pages 20-27. Page 28,line 11 to page 29,line 7 refers to the use of various types of samples and their measurement. Figure 1 shows data derived when using the claimed method on samples obtained from a human patient. Page 28, line 3 to page 33, line 2 describes kits and their contents contemplated for use with the claimed methods. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

Considering that new claims 36-43 are limited to the use of a peptide consisting of amino acid residues 2-14 of SEQ ID NO:1, a search of these claims would encompass this specific peptide. As was mentioned in the Response filed on February 4,200, the instant application is related, in claim format, to several other pending applications. In an effort to maintain equivalent scope in these applications, Applicants would appreciate the Examiner's reconsideration of the restriction requirement in light of the overlapping search and rejoin under *Ochai* claim 1 which is drawn to a specific peptide to claims 36-43 which are drawn to methods and kits limited to use of the specific peptide of claim 1.

Sequence Compliance

Applicants have reviewed the entire specification including the figures and the claims for sequence disclosures. The only sequence found to be disclosed is the amino acid sequence identified as SEQ ID NO:1. Applicants provided a Sequence Listing (in both paper and computer readable form) disclosing SEQ ID NO:1 on April 19, 2002. However, Applicants noted that the first and last amino acid residues of SEQ ID NO:1 (as disclosed by the sequence shown in the figures) were not included in the originally filed Sequence Listing. Applicants herein provide a diskette containing a substitute Sequence Listing in electronic computer readable form to replace the previously submitted copy (filed on

April 19, 2002). The diskette submitted herewith contains a Sequence Listing which adds the first and last amino acid residues (shown in the figures) to SEQ ID NO:1. As shown in Figure 1, the marker identified in patient sera consists of amino acid residues 2-14 of SEQ ID NO:1. When carrying out mass spectrometric procedures, it is possible to fragment a whole molecule, depending upon the enzyme used for digestion. A sequence is often predicted from these fragments but often the sequence is not identified completely. It is conventional in the art to show the missing portions of the predicted sequence in parentheses. The first (D) and last (G) amino acid residues of SEQ ID NO:1 are predicted residues as indicated by the parentheses in Figure 1. The peptide sequence without the predicted first and last amino acid residues was shown in the original specification at page 27, line 18 and is shown in the figures with the first and last predicted amino acid residues. Thus, no new matter is added, the substitute Sequence Listing is for the purpose of clarifying the use of parentheses only. Applicants also herein provide a substitute paper copy of the Sequence Listing as contained on the diskette filed herewith. The computer readable form of the substitute Sequence Listing is identical to the paper copy of the substitute Sequence Listing. The amendments to the claims and specification limiting the marker sequences to specific amino acid residues are also made for the purpose of clarification only. The claims as herein amended limit

the marker sequence to amino acid residues 2-14 of SEQ ID NO:1.

Information Disclosure Statement

On page 3 of the Office Action mailed on March 11, 2003, the Examiner indicates that the IDS filed on August 13,2001 in paper #5 was not found in the application. Applicants have no record of an IDS filed on August 13, 2001 in the instant application. Two IDS statements were filed; the first on February 4, 2002 and the second on December 9, 2002, both of which have been considered by the Examiner.

Rejections under 35 USC 112 (second paragraph)

Claims 3-9, 18-28 and 33-35, as originally presented, stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleges that the terms "evidencing" and "characterizing" in claims 3-5 are vague and indefinite because it is not clear as to what "evidencing" and "characterizing" encompasses. The Examiner states if the method merely detects myocardial infarction or renal failure via a biopolymer marker as (defined in the disclosure) it is suggested that the phrases are replaced with "detecting" in order to clarify applicants intended meaning.

Claims 3-5 have been canceled and the terms "evidencing" and "characterizing" are not recited in any of the remaining pending claims.

The Examiner alleges that the term "regulation" in claim 35 is a relative term which renders the claim indefinite. The term "regulation" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to how the measurement of the biopolymer marker will further serve to control the absence and/or presence of the aforementioned biopolymer marker or analyte thereof. It is suggested by the Examiner that the claim merely recite detection of the biopolymer.

Claim 35 has been canceled and the term "regulation" is not recited in any of the remaining pending claims.

Accordingly, applicants have now clarified the metes and bounds of the claims and respectfully request that the above-discussed rejections under 35 U.S.C. 112 (second paragraph) be withdrawn.

Rejection under 35 USC 112 (first paragraph)

Claims 3-9, 18-28 and 33-35, as originally presented, stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was allegedly not described in the

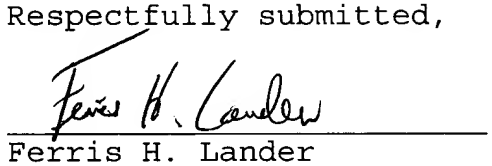
specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants are currently in the process of preparing a Declaration Under 37 CFR 1.132 in order to provide evidence of the absence of the 1350 dalton biopolymer marker(amino acid residues 2-14 of SEQ ID NO:1) in normal (non-diseased) human sera and will forward this Declaration to the Examiner as soon as it is complete. Applicants will further address the rejection under U.S.C. 112, first paragraph at the time the Declaration is submitted.

SUMMARY

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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